

## REMARKS

Claims 12, 14, 16-18, and 20-37 were pending. The Examiner rejected claims 12, 14, 17, 18, 20, 22-27, 29-34, 36, and 37, and withdrew claims 16, 21, 28, and 35 as drawn to non-elected subject matter. Applicants have herein amended claim 27 to delete the term "eosinophil". No new matter has been added.

Applicants thank the Examiner and her Supervisor for the courtesy of a telephonic interview held on January 7, 2010, in which the pending rejections and the claims were discussed. While no decision as to allowability of one or more of the claims was reached, Applicants appreciate the Examiner's and the Supervisor's comments and careful consideration of the present case. Applicants also agree with the Interview Summary mailed January 13, 2010.

In light of the amendments and the remarks herein, Applicants respectfully request reconsideration and allowance of the pending claims.

### Withdrawal of Claims

The Examiner withdrew claims 16, 21, 28, and 35 as drawn to non-elected subject matter. Applicants respectfully disagree. The Restriction Requirement dated July 17, 2007 stated that Group II included original claims 12-17, drawn to a "method of treatment" using a c-Kit kinase inhibitor. The Restriction Requirement went on to indicate that if Group II was elected, a species of cancer for claims 13-14 (*see* page 6 of the Restriction Requirement) was required. Original claim 16 was directed to a method of treating mastocytosis, allergy, or asthma, and was included in the claims indicated by the Examiner to fall in Group II (*i.e.*, claims 12-17). Applicants subsequently elected Group II, and indicated that claims 12-15 and 17 of Group II read on the species of small cell lung cancer. In subsequent Office Actions, the Examiner did not withdraw claim 16 as drawn to non-elected subject matter or issue another Restriction Requirement. Applicants respectfully assert that while claim 16 does not read on the elected species, it does fall within the elected Group II, drawn to a method of treatment using a c-Kit kinase inhibitor. Applicants respectfully request that the Examiner reconsider the withdrawal of claims 16, 21, 28, and 35.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 12, 14, 17-18, 20, 22-27, 29-34, and 36-37 as failing to comply with the written description requirement, and in particular, for lacking description of the limitations: (1) “determining if the patient’s cancer expresses c-Kit kinase or a mutant c-Kit kinase;” (2) “if the cancer is determined to express c-Kit kinase or a mutant c-Kit kinase;” and (3) a cell that is a mast cell or an eosinophil. Applicants respectfully disagree. As discussed during the interview, with respect to (1) and (2), Applicants respectfully assert that paragraphs [0038], [0043] and original claim 15 of the application (US Publication 2004/0253205) provide support for such limitations. With respect to (3), Applicants have amended the claim to remove the limitation “eosinophil,” and further refer the Examiner to paragraphs [0018] – [0020], [0115] and original claim 16 for support for mastocytosis, allergy, asthma, and mast cells. Applicants respectfully assert that one having ordinary skill in the art would understand the Applicants to be in possession of the claimed invention. Withdrawal of the rejections is respectfully requested.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 12, 14, 17-18, 20, 22-27, 29-34, and 36-37 under 35 U.S.C. § 103 as being unpatentable over Funahasi (WO 02/032872, hereinafter “Funahasi”) in view of Hibi *et al.* (“Hibi”). In particular, the Examiner reiterated her previous rejections and comments regarding the teachings of Funahasi and Hibi, including that Funahasi discloses the elected compound for use in treating cancers, including lung cancer, and as a pulmonary treatment agent, and that Hibi discloses that c-Kit is expressed in small cell lung cancer. The Examiner concluded that one of ordinary skill in the art would have been motivated to use the elected compound in the claimed methods since Funahasi teaches it as an effective pulmonary agent and Hibi teaches c-Kit expression in the elected small cell lung cancer. Moreover, the Examiner acknowledged that Funahasi did not explicitly disclose the c-Kit inhibiting properties of the elected compound, but alleged that the c-Kit inhibiting properties of the elected compound were inherent properties.

As indicated in the interview, Applicants respectfully disagree with the rejections. Independent claims 12 and 17, as presently pending, recite steps of determining if a patient's cancer or a cell, respectively, expresses c-Kit kinase or a mutant c-Kit kinase. As acknowledged by the Examiner, Funahasi is silent as to the inhibitory activity of the elected compound on c-Kit kinase. Moreover, Funahasi also does not disclose the expression of c-Kit in any cancer, let alone the elected small cell lung cancer, nor does Funahasi disclose or suggest that one should determine if a patient's cancer or a particular cell of interest expresses c-Kit kinase or a mutant c-Kit kinase before administration of one of the Funahasi compounds. One of ordinary skill in the art would thus find no reason or motivation to modify the cancer treatment methods in Funahasi to perform an additional step of determining c-Kit or mutant c-Kit expression prior to administration of a Funahasi compound for treating a cancer. The Examiner has provided no logical rationale why one having ordinary skill in the art would so modify the treatment methods of Funahasi to include the recited determining step given Funahasi's silence as to the c-Kit inhibiting property of the recited molecule.

Hibi fails to cure the deficiencies of Funahasi. Merely because Hibi teaches that c-Kit is expressed in small-cell lung cancer provides no logical reason for one having ordinary skill in the art to modify the methods of Funahasi to add an additional step to determine if a patient's cancer or a cell expresses c-Kit before administration of the recited compound, particularly given the fact that both Funahasi and Hibi are silent as to the c-Kit inhibiting properties of the recited compound. The Examiner has provided no rationale why the mere fact that small cell lung cancer expresses c-Kit would prompt one having ordinary skill in the art to insert a step of determining if a patient's cancer or a cell expresses c-Kit prior to administering a Funahasi compound for treating cancer, when both Funahasi and Hibi are silent as to the c-Kit inhibiting properties of the elected compound. Applicants respectfully assert that such a rationale would improperly render obvious any method wherein any biomarker for a cancer is evaluated before treatment with any cancer drug, as the Examiner has provided no logical nexus here between the particular biomarker measuring step and the particular drug for treatment. Hibi's total lack of disclosure and appreciation of such a c-Kit inhibiting inherent property precludes a finding that

one having ordinary skill in the art would be motivated by Hibi's teachings to modify Funahasi to include a step of determining c-Kit or mutant c-Kit expression. Applicants note that the Federal Circuit has held that the inherency of an advantage and its obviousness are entirely different questions (*In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990)). "[A] retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination" (*In re Newell*, 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989)). Accordingly, Applicants respectfully assert that the Examiner has not made out a *prima facie* case of obviousness, and request withdrawal of the rejections.

### CONCLUSION

Applicants respectfully assert that all claims are in condition for allowance, which action is hereby requested. The Examiner is invited to telephone the undersigned attorney if such would expedite prosecution.

Enclosed is a Petition for Extension of Time (2 months). Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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/Teresa A. Lavoie/  
Teresa A. Lavoie, Ph.D.  
Reg. No. 42,782

Fish & Richardson P.C.  
3200 RBC Plaza  
60 South Sixth Street  
Minneapolis, Minnesota 55402  
Telephone: (612) 335-5070  
Facsimile: (877) 769-7945